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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,725	10/04/2000	Robert g. Whirley	TRI-0255-UT	7345

69404 7590 09/18/2008

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EXAMINER	
PROCTOR, JASON SCOTT	
ART UNIT	**PAPER NUMBER**
2123	

MAIL DATE	DELIVERY MODE
09/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/679,725	WHIRLEY ET AL.	
	Examiner	Art Unit	
	JASON PROCTOR	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-27,29-39,41,42,54-65,67-81,83-94,96-98 and 112-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-27,29-39,41,42,54-65,67-81,83-94,96-98 and 112-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-123 were rejected in the Office Action entered on 6 December 2007.

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 26 August 2008 has been entered.

The 26 August 2008 submission has amended claims 1, 16, 31, 54, 70, and 86; and presented new claims 124-127.

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-127 are pending in this application. Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-127 are rejected.

Response to Arguments – 35 USC § 102

1. In response to the previous rejection of claims 1, 16, 31, 54, 70, and 86 under 35 U.S.C. § 102 as being anticipated by "Interface Mechanics in Lower-Limb External Prosthetics: A Review of Finite Element Models" by Santosh G. Zachariah and Joen E. Sanders, Applicants argue primarily that:

> [...] Zachariah does not disclose or suggest a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system and generates a geometric model of said anatomical feature(s). Neither does Zachariah disclose or suggest a stress/strain/deformation

> analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, loads data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said medical device. [here underlined text is amended claim language]

This argument has been fully considered and has been found persuasive.

The previous rejections under 35 U.S.C. § 102 have been withdrawn.

Response to Arguments – 35 USC § 103

2. In response to the rejection of claims 1-3, 5-7, 9-10, 14, 112-113; 16-18, 20-22, 24-25, 29, 114-115; 31-37, 41, 116-117; 54, 56, 58-60, 62-63, 67-68, 118; 70, 72, 74-76, 78-79, 83-84; 86, 88-92, 96-97, and 119 under 35 U.S.C. § 103 as unpatentable over "Balloon-Artery Interactions During Stent Placement : A Finite Element Analysis Approach to Pressure, Compliance, and Stent Design as Contributors to Vascular Injury" by Campbell Rogers, David Y. Tseng, James C. Squire, and Elazer R. Edelman (hereafter referred to as Rogers) in view of US Patent No. 5,594,651 to St. Ville, Applicants argue primarily that:

> Applicants suggest that there is no motivation to combine Rogers with St. Ville, but that even if combined, the combination fails to disclose or suggest all limitations of the rejected claims. […] As Rogers is directed to modeling contact stress for predicting tissue injury and St. Ville is directed to methods for optimizing manufacturing parameters, there is no motivation to combine the references.

The Examiner respectfully traverses this argument as follows.

As stated in the previous rejection, motivation to combine the references is explicitly provided by St. Ville, such as to quickly produce the required model for analysis [*"The use of such computer aided design software packages permits a geometric model of an object or part to be defined by a user and modified quickly and results in generation of geometry data which can be converted to formats useful in a computer aided manufacturing step and/or to formats useful to a finite element method step, which steps are discussed in greater detail below."* (St. Ville,

column 9, lines 22-28); *"For example, the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip... This image data may be converted to a format usable by the CAD software package or may be directly converted to a format usable by a finite element software package..."* (column 9, lines 31-38)]. Therefore, it would have been obvious to a person of ordinary skill in the art to use the teachings of St. Ville to generate a geometric model and a finite element model or mesh to quickly acquire the necessary models for the simulation method taught by Rogers.

In further detail, when the method of Rogers predicts that the modeled stent may produce unacceptable tissue injury, a new stent model may be tried. St. Ville teaches a method for quickly producing a model suitable for study by Roger's method. Thus a person of ordinary skill would be motivated to combine the teachings of these two references.

Applicants further argue that:

> [The combination of references does not] disclose or suggest a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system and generates a geometric model of said anatomical feature(s). Neither does Zachariah [*sic.* Presumed to mean "the combination of Rogers and St. Ville"] disclose or suggest a stress/strain deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, loads data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said medical device. [here underlined text is amended claim language]

The Examiner finds this argument persuasive in part.

The combination of references clearly teaches a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system and generates a geometric model of said anatomical features [*"First, a finite element model of the normal bone geometry ... is created."* (St. Ville, column 16, lines 44-45); *"For example, the*

initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip using, for example, a Siemens Somatom DR3 or a GE 9800 CT scanner. This image data may be converted to a format usable by the CAD software package or may be converted to a format usable by finite element software package (for example, a PDA-PATRAN (available from PDA Engineering) format) to be described below." (St. Ville, column 9, lines 31-38)]; [*Our model included input of the following: individual stent-strut width and thickness and interstrut distances of the corrugated-ring and slotted-tube stents described above, Young's modulus and Poisson's ration for the balloon material, arterial-wall thickness, Young's modulus (circumferential) and Poisson's ratio for the artery, and pressure loaded into the balloon."* (Rogers, page 379, left column, "Finite Element Analysis")].

Neither Rogers nor St. Ville expressly teaches simulating interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system.

Applicants' remarks referring to various dependent claims rejected under 35 U.S.C. § 103 as being obvious over, *inter alia*, Rogers in view of St. Ville, submit that the other references do not remedy the deficiencies of Rogers in view of St. Ville. For the reasons shown above, these arguments are considered persuasive.

All previous rejections under 35 U.S.C. § 103 relied upon at least Rogers in view of St. Ville. All previous rejections under 35 U.S.C. § 103 are withdrawn. A new search of the prior

art has revealed references that teach the claimed simulation of a cardiovascular cycle. Accordingly, new grounds of rejection have been entered below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 124-127 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 124 recites "recreating a ***large number*** of dynamic expansion and contraction cycles of the vascular system," where the phrase "large number" is a relative term not defined by the claim. This claim language is indefinite.

4. Claim 125 recites "an amount of cycles that would meet or exceed the amount of cycles that ***would be expected in the individual's lifetime***." The phrase "the individual's lifetime" lacks antecedent basis. The "amount of cycles" is defined using relative terminology not defined by the claim. This claim language is indefinite.

5. Claim 126 recites "simulating testing ***necessary or desirable for FDA approval***." This is clearly vague and indefinite terminology where the scope of invention is defined indirectly according to the needs or desires of the FDA, which may change at a later date. This claim language is indefinite.

6. Claim 127 recites "simulating testing ***necessary to establish equivalence*** of the medical device with an approved medical device" where the amount of testing covered by the claim is described using relative terminology. This claim limitation may require, for example, 1 test (where the device performs perfectly) or infinite tests (where the device is fatally flawed). This language does not describe any definite boundaries for the scope of the invention. This language is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

7. Claims 1-3, 5-7, 9-10, 14, 112-113; 16-18, 20-22, 24-25, 29, 114-115; 31-37, 41, 116-117; 54, 56, 58-60, 62-63, 67-68, 118, 126-127; 70, 72, 74-76, 78-79, 83-84, 124-125; 86, 88-92, 96-97, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Balloon-Artery Interactions During Stent Placement : A Finite Element Analysis Approach to Pressure, Compliance, and Stent Design as Contributors to Vascular Injury" by Campbell Rogers, David Y. Tseng, James C. Squire, and Elazer R. Edelman (hereafter referred to as Rogers) in view of US Patent No. 5,594,651 to St. Ville, and further in view of US Patent No. 6,381,562 to Keane.

Regarding claims 1, 3, 16, 18, 31, 54, 56, 70, 72, and 86, Rogers teaches a system for analyzing medical devices [*"...we have used finite element analysis to model how balloon-artery contact stress and area depend on stent-strut geometry, balloon compliance, and inflation pressure."* (abstract)], comprising:

A stress/strain/deformation analyzer [*"Automatic Dynamic Incremental Nonlinear Analysis software (ADINA 7.0, ADINA R&D, Inc) on a dedicated workstation (Silicon Graphics)"* (page 379, left column, "Finite Element Analysis")] that receives a finite element model or mesh, material properties of an anatomical feature(s) and a medical device, load data on said anatomical feature(s), and/or said medical device [*"Our model included input of the*

following: individual stent-strut width and thickness and interstrut distances of the corrugated-ring and slotted-tube stents described above, Young's modulus and Poisson's ration for the balloon material, arterial-wall thickness, Young's modulus (circumferential) and Poisson's ratio for the artery, and pressure loaded into the balloon." (page 379, left column, "Finite Element Analysis")] and simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device [*"The FEA model used in this analysis included both displacement and pressure loading to represent arterial displacement and balloon extrusion between the struts, respectively."* (page 379, left column); *"Constant step-time functions were used to control artery displacement and balloon extrusion between struts during analysis. The correlations of maximum contact stress and contact area with balloon pressure and the distance between adjacent stent struts at different Young's moduli of balloon materials were analyzed."* (page 379, left column); *"FEA was used to investigate in a continuous fashion independent effects of distance between stent struts, balloon-material properties, and balloon inflation pressures on balloon-artery surface stress and contact area."* (page 380, right column, "Finite Element Analysis"); Figure 4; etc.].

Rogers does not expressly teach ***the claimed geometry generator and mesh generator***.

St. Ville teaches a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature [*"First, a finite element model of the normal bone geometry ... is created."* (column 16, lines 44-45); *"For example, the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip using, for example, a Siemens Somatom DR3 or a GE 9800 CT*

scanner. This image data may be converted to a format usable by the CAD software package or may be converted to a format usable by finite element software package (for example, a PDA-PATRAN (available from PDA Engineering) format) to be described below." (column 9, lines 31-38)]; and

A mesh generator that receives said geometric model of said anatomical features and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical features and said geometric model of said medical device [*"A finite element model is again created, but now includes another layer, namely, the artificial hip embedded in the cancellous bone area."* (column 17, lines 4-6); FIGS. 4A, 4B].

Rogers and St. Ville are analogous art because both are directed to the application of finite element analysis in medical prosthetics.

It would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the teachings of Rogers and St. Ville to arrive at the claimed invention because St. Ville expressly teaches that the methods taught therein quickly produce the required models for analysis [*"The use of such computer aided design software packages permits a geometric model of an object or part to be defined by a user and modified quickly and results in generation of geometry data which can be converted to formats useful in a computer aided manufacturing step and/or to formats useful to a finite element method step, which steps are discussed in greater detail below."* (column 9, lines 22-28); *"For example, the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip... This image data may be converted to a format usable by the CAD software package or may be directly*

converted to a format usable by a finite element software package..." (column 9, lines 31-38)]. Therefore, it would have been obvious to a person of ordinary skill in the art to use the teachings of St. Ville to generate a geometric model and a finite element model or mesh to quickly acquire the necessary models for the simulation method taught by Rogers.

Rogers in view of St. Ville does not explicitly teach simulating an interaction between said anatomical feature(s) and said medical device ***over at least one dynamic expansion and contraction cycle of the vascular system***.

Keane discloses simulation of at least one dynamic expansion and contraction cycle of the vascular system [*"Almost all organisms have system for channeling or otherwise controlling the movement of mass and/or energy in or around the organism. These systems are referred to herein as 'bio-transport systems' (BTS), and include, for example, circulatory system..."* (column 1, lines 18-26); *"More specifically, the present invention applies finite-element techniques along with first principles and empirical relationships to a bio-transport system to construct mathematical representations of one or more bio-transport dynamics in and around the bio-transport system based on user-characterized elements representing the bio-transport system."* (column 3, lines 1-17); *"The driving force for fluid motion is traced back to a prime mover, for example, the pumping action of the heart, or to boundary conditions at "input/output" elements which may be used of the simulator is configured to represent part of a circulatory system, for example, a region of microcirculation."* (column 11, lines 25-39)].

Keane and Rogers in view of St. Ville are analogous art because both are directed to finite element simulation of anatomical features.

It would have been obvious to a person of ordinary skill in the art to combine the teachings of Keane with Rogers in view of St. Ville because, when implementing the system of Rogers in view of St. Ville, it would have been apparent that the dynamic behavior of the cardiovascular system with a stent in place could cause tissue damage (discussed explicitly by Rogers in "In Vivo Analysis of Endothelial Cell Denudation"), while Keane teaches a method of simulating that same dynamic behavior which could contribute to tissue damage. Further, Keane expressly provides motivation, such as to experiment and practice with a bio-transport system in simulation, without the attendant time constraints, risks, and difficulties of dealing with a real bio-transport system in a living organism (column 2, lines 57-64). That is, Keane explicitly motivates a person of ordinary skill in the art to combine the disclosed bio-transport simulation with whatever "experiments" are called for in the prior art, such as a designing a cardio-vascular stent that does not cause tissue damage in the artery and is made with acceptable manufacturing parameters.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the teachings of Keane, Rogers and St. Ville to arrive at the invention specified in claim 1.

Claims 16, 31, 54, 70, and 86 recite systems and the methods performed by those systems which are substantially identical to the system of claim 1 or present limitations that have been addressed above. These claims are rejected rationale similar to that given above for claim 1.

Claims 18, 56, and 72 reiterate the limitations of claim 3 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 2, 17, and 32 St. Ville teaches that the geometric model of said anatomical features is an idealized geometric model [*"First, a finite element model of the normal bone geometry ... is created. The stiffness properties of each layer are then defined... These stiffness properties and loads are known quantities which have been published in numerous journals..."* (column 16, lines 44-58)].

Claims 17 and 32 reiterate the limitations of claim 2 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 5-7, 20-22, 33-35, 58-60, 74-76, and 88-90, Rogers teaches that the prosthesis is an endovascular prosthesis, a stent graft, and a cardiovascular stent (abstract).

Regarding claims 9, 24, 36, 62, 78, and 91, St. Ville teaches that the mesh generator includes three-dimensional finite modeling software [*"Other suitable software packages for generating the finite element model include MSC/NASTRAN [...], ABAQUS [...], and ANSYS [...]."* (column 9, lines 54-59)].

Regarding claims 10, 25, 37, 63, 79, and 92, Rogers teaches that the stress/strain/deformation analyzer is a non-linear finite element modeling software [*"Automatic*

Dynamic Incremental Nonlinear Analysis software (ADINA 7.0, ADINA R&D, Inc) on a dedicated workstation (Silicon Graphics)" (page 379, left column, "Finite Element Analysis")].

Regarding claims 67, 83, 96, 112, 114, and 116, Rogers teaches that the stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate said stresses strains, and deformations of said medical device [*"Automatic Dynamic Incremental Nonlinear Analysis software (ADINA 7.0, ADINA R&D, Inc) on a dedicated workstation (Silicon Graphics)"* (page 379, left column, "Finite Element Analysis")].

Regarding claims 14, 29, 41, 68, 84, and 97, Rogers teaches a visualization tool that receives said simulated stresses, strains, and deformations of said medical device from said stress/strain/deformation analyzer and displays one or more of said stresses, strains, and deformations of said medical device via visual representation (Figure 4).

Regarding claims 113, 115, 117, 118, and 119, St. Ville teaches that the simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations [*"mechanical forces shown in FIGS. 4A and 4B during walking and rising from a chair."* (column 8, lines 25-30)].

Claims 115, 117, 118, and 119 reiterate the limitations of claim 113 which have been addressed above. These claims are rejected rationale similar to that given above for claim 113.

Regarding claims 124-127, at least Keane teaches performing simulations over a "long term" involving a "large number" or dynamic expansion and contraction cycles of the vascular system [*"It should be obvious to those skilled in the art that the simulation model must be constructed before it can be run, and that, once constructed, it can be run repeatedly without being 'reconstructed.'"* (column 4, lines 1-12)], simulating "a number of cycles that would be expected in the individual's lifetime" (column 4, lines 1-12), simulating "necessary or desirable" for FDA approval (column 4, lines 1-12), and testing necessary to establish equivalence of the medical device with an approved medical device (column 4, lines 1-12).

8. Claims 4, 19, 57, and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of US Patent No. 5,880,976 to DiGioia III et al. (DiGioia).

Rogers in view of St. Ville does not expressly teach acquiring three-dimensional volumetric data via MRI.

DiGioia teaches several techniques of acquiring structural data of a skeletal structure, including MRI [*"Commonly used tomographic techniques include computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomographic (PET), or ultrasound scanning of the joint and surround structure. The tomographic data from the scanned structure generated by the skeletal data source 13 is provided to the geometric planner 12 for use in producing a model of the skeletal structure."* (column 7, lines 8-14)].

Rogers in view of St. Ville and DiGioia are analogous art because both are directed to modeling prosthetic implants.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the imaging techniques taught by DiGioia in the modeling system of Rogers in view of St. Ville because DiGioia expressly teaches how to provide for the proper placement and implantation of the joint components to provide an improved range of motion and usage of the joint following joint reconstruction, replacement, and revision surgery (DiGioia, column 4, lines 50-60).

Claims 19, 57, and 73 reiterate the limitations of claim 4 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 4.

9. Claims 8, 23, 61, and 77 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based upon *In Vivo* MR Images" by Seung Lee et al. (Lee).

Rogers in view of St. Ville does not expressly disclose that the geometry generator is a software application which generates surface points from the three-dimensional volumetric data, which are then converted into stereolithography, slice files, IGES files or a combination thereof.

Lee teaches methods for creating a CFD mesh of a blood vessel based on in vivo measurements taken by magnetic resonance imagine (abstract). Lee teaches generating 3D-lumen geometry using Mimics (page 1, right column) from MR imaging data (page 1, left and right columns).

Rogers in view of St. Ville and Lee are analogous art because both are directed to imaging and modeling of anatomy.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the use of MIMICS to interpret MRI data and generate geometry as taught by Lee in the modeling system of Rogers in view of St. Ville because Lee expressly teaches that "the goal of this study was to develop an automated mesh generation technique based on measurements of *in vivo* lumen geometry using MR," (page 1, left column) and therefore provides an automation solution to that step of the modeling process.

Claims 23, 61, and 77 reiterate the limitations of claim 8 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 8.

10. Claims 11-12, 26-27, 38-39, 64-65, 80-81, and 93-94 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 9-10, 24-25, 36-37, 62-63, 78-79, and 91-92 above, and further in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin).

Regarding claim 11, Rogers in view of St. Ville does not expressly disclose that the three-dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.

Raboin teaches several computational mechanics codes for finite element analysis (page 2 of 13, "Structural Problems, Computer Solutions") including DYNA3D (pages 3-6 of 13, "Two Classes of Codes") and NIKE3D (pages 6-8 of 13, "NIKE3D for Biomechanics") for "studying dynamic, finite deformations, [which] can model the behavior of joint tissues and bones subjected to different loads and joint movement with and without prosthetic implants (pages 6-7 of 13).

Rogers in view of St. Ville and Raboin are analogous art because both are directed to modeling of prosthetic joints.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use one of the computational mechanics codes taught by Raboin in the modeling system of Rogers in view of St. Ville because Raboin expressly teaches that the finite element methods have "powerful versatility" that can model "numerous nonlinear material behaviors" (page 2 of 13) and therefore allow greater flexibility in performing a wider variety of simulations.

Claims 26, 38, 64, 80, and 93 reiterate the limitations of claim 11 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 11.

Claims 12, 27, 39, 65, 81, and 94 have been previously interpreted as recited features inherent in DYNA3D and NIKE3D and are therefore rejected for rationale similar to that given above for claim 11. (See Office Action, 7 February 2006, page 5)

11. Claims 15, 30, 42, 69, 85, and 98 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rogers in view St. Ville as applied to claims 14, 29, 41, 68, 84, and 97 above, and further in view of "GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual" by Douglas E. Speck and Donald J. Dovey (Dovey).

Rogers in view St. Ville does not expressly disclose the use of interactive software for visualizing finite element analysis results of three-dimensional grids.

Dovey teaches that GRIZ is "a general-purpose post-processing application supporting interactive visualization of finite element analysis results on unstructured grids. GRIZ calculates

and displays derived variables for a variety of analysis codes. Currently, GRIZ works with the family of Methods Development Group (MDG) analysis codes, including DYNA3D, NIKE3D, and TOPAZ3D." (page 1, "Introduction"). Dovey teaches that GRIZ displays the results of various parameters (page 21, "Results Command"), including various stress results variables (*ex.* "sx", page 21); strain variables (*ex.* "ex", page 22); and deformation (*ex.* "dispx", page 24).

Rogers in view of St. Ville and Dovey are analogous art because both are directed toward finite element analysis.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use GRIZ as taught by Dovey to visualize the results of the modeling system of Rogers in view of St. Ville because Dovey expressly teaches that "GRIZ provides flexible control of mesh materials on an individual basis, allowing the user to concentrate analysis and visual focus on important subsets of the mesh. GRIZ incorporates the ability to animate all representations over time," thereby enhancing the analysis capabilities present in the system taught by Rogers in view of St. Ville to increase productivity.

Claims 30, 42, 69, 85, and 98 reiterate the limitations of claim 15 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 15.

12. Claims 55, 71, 87, and 120-123 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 54, 70, and 86 above, and further in view of "Failure of All-ceramic Fixed Partial Dentures *in vitro* and *in vivo*: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen).

Regarding claims 55, 71, and 87, Rogers in view of St. Ville does not expressly disclose performing a simulation to the point of failure of the medical device.

Sorensen teaches performing a finite element analysis (FEA) of fixed partial denture medical devices (abstract) to the point of failure of the device [*"Weibull failure probability (P_f) calculations, incorporating FEA stress profiles... Observations from failed clinical restorations provided critical guidance in validating a laboratory test and focusing a mathematical failure model."* (abstract); *"Fig. 3 is the finite element solution obtained when the abutment was rigidly fixed..."* (page 1255, right column – page 1256, left column, "Results"); *"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion")].

Rogers in view of St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of Rogers in view of St. Ville because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Regarding claims 120-123, Rogers in view of St. Ville does not expressly disclose performing a failure mode simulation.

Sorensen teaches a geometric model of an *in vitro* failure mode test [*"Figure 4. Finite element solution when the abutment tooth is allowed to rotate... This result corresponds more closely to the fractographic findings* [failure mode] *than does the solution in Fig. 3"* (Fig. 4, caption)].

Sorensen teaches a step of simulating stresses, strains, and deformations imposed on said candidate medical device design in said *in vitro* failure mode test [*"Finite element analysis (FEA) of the laboratory FPDs found that maximum principal tensile stresses would occur at locations consistent with the fractographic observations..."* (abstract)].

Sorensen teaches comparing simulation data generated by said step of simulating and additional simulation data generated by said step of simulating an *in vitro* failure mode test [*"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion"); *"Fig. 5 is a plot of the probability of failure* vs. *failure load for data from the 20 laboratory FPDs along with calculated failure probabilities based upon the finite element results with abutment rotation allowed. Probabilities for the* in vitro *data were simply evaluated..."* (page 1256, left column, "Results")].

Sorensen teaches that the *in vitro* failure mode test parameters, while not part of the disclosed model, are known in the art and the absence of this influence is a criticism of the disclosed model [*"Possible effects of damage accumulation due to cyclic loading (Suresh, 1991) are also not part of the model. These same criticisms hold for the laboratory test as well."* (page 1257, right column, "Discussion")].

Rogers in view of St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of Rogers in view of St. Ville because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Conclusion

The prior art reference "Numerical Simulation of the Blood Flow in the Human Cardiovascular System" by Martin Zacek (1995) teaches one method for simulating a whole cardiovascular system as known in the prior art (abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Proctor whose telephone number is (571) 272-3713. The examiner can normally be reached on 8:30 am-4:30 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached at (571) 272-3753. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: 571-272-2100. Information regarding the status of

an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jason Proctor/
Examiner
Art Unit 2123

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